A randomised controlled trial comparing the clinical and cost-effectiveness of the Avaulta anterior mesh and the standard anterior colporraphy for the primary surgical treatment of a cystocele stage >= 2

Published: 20-02-2007
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To compare the clinical and cost-effectiveness of an anterior colporraphy repair with a cystocele repair with the use of the non-absorbable synthetic Avaulta® mesh.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON30439

Source
ToetsingOnline

Brief title
Avaulta versus anterior colphorraphy

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
cystocele, vaginal prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anterior prolapse surgery, cystocele, polypropylene mesh, Randomized controlled trial

Outcome measures

Primary outcome

The primary endpoint of the study is the number of women who will have a

recurrence, defined as a stage >= 2 anterior vaginal prolapse at 2 years

follow-up.

Secondary outcome

Secondary endpoints are;

- The effect of surgery on urogenital symptoms and quality of life

- Complications of surgery (direct and medium term)

- Cost-effectiveness analysis.

Study description

Background summary

After a standard surgical anterior colporraphy for an anterior vaginal wall prolapse (cystocele) grade 2 or higher, one-third of women will have an anatomical recurrence within 2 years after primary surgery. The use of a non-absorbable synthetic polypropylene mesh has been shown to be effective in repeat surgery for genital prolapse, with a recurrence rate between 3-12%. However, a comparative study between the anterior colporraphy and surgery with a non-absorbable synthetic mesh as primary treatment for an anterior vaginal wall prolapse has not been conducted.

Study objective

To compare the clinical and cost-effectiveness of an anterior colporraphy repair with a cystocele repair with the use of the non-absorbable synthetic Avaulta® mesh.

Study design

Single-blinded, multicenter, randomised controlled trial

Intervention

Women are either allocated to a group who will undergo a classic anterior colporraphy repair or a group in which the Avaulta® mesh is used.

Study burden and risks

All women participating will have their regular pre- and postoperative care, which consists of a scheduled visit after 6 weeks and one year. In addition an extra visit after 6 months and 2 years is planned. Before surgery and during all scheduled 4 postoperative visits, the women will undergo a gynaecologic physical examination, POP-Q assessment and fill in questionnaires related to the study. In the direct postoperative period, a diary for 7 days will be filled in by the woman. Apart from the use of questionnaires, no addition diagnostic tests are planned. In relation to the use of the Avaulta® mesh, women with the mesh have a slight increased risk of repeated surgery in relation to mesh erosion problems as compared to women after a classical repair.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women aged 40-80 years
Cystocele stage >= 2 according to POP Q classification
No previous anterior colporraphy
Good understanding of Dutch language in word en writing

Exclusion criteria

1. Women with childbearing potential who do not use adequate contraceptive measures (hormonal contraceptives, barrier methods (condoms), intra uterine device, male vasectomy, sterilisation).
2. History of major gynaecological or urological surgery, with the exception of a hysterectomy for reasons other than a genital prolapse.
3. History of cancer or severe cardiopulmonary disease
4. Conditions that might interfere with a successful conduction and completion of the study in the opinion of the specialist (language problems, cognitive dysfunction, etc)
5. Recurrent lower urinary tract infections (> 3 culture proven infections/year)
6. Maximum bladder capacity < 300 ml (bladder diary)
7. Urinary stress incontinence with an indication for surgical correction.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2007
Enrollment:	115
Type:	Actual

Medical products/devices used

Generic name:	Avaulta anterior
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-02-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-11-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13436.041.06